who join me in this effort, including my co-chairs from the Study Group on Public Health, KAY GRANGER and JIM MCGOVERN; my colleagues, JIM MORAN from the Prevention Caucus and DIANA DEGETTE and MIKE CASTLE from the Diabetes Caucus.

We share a passion for improving public health and preventing chronic disease.

I also thank The Trust for America's Health and the Campaign for Public Health, in addition to over 150 public health organizations that have endorsed this resolution.

Mr. Speaker, the future health of our Nation depends on the priorities we set as we begin the process of health care reform.

By passing H. Res. 1381 today, we are sending an important message to the new 111th Congress that Public Health and Prevention must be a priority in any health reform package.

I urge my colleagues to vote ''yes'' on the passage of H. Res. 1381. We cannot solve the health care crisis in this country until we get serious about prevention.

Mr. BURGESS. Mr. Speaker, I yield myself such time as I may consume, and I also rise in support of House Resolution 1381, a resolution expressing the sense of the House that there should be an increased public and private commitment prioritizing prevention and public health for all people in the United States.

Each year almost 2 million people in the United States die from chronic diseases that are often preventible and also account for almost three-quarters of health care spending. It costs the United States almost $1 trillion a year in lost productivity that erodes our national competitiveness.

In an effort to alleviate chronic diseases, Americans need to eat right, quit smoking, and get exercise. You probably don't need to be an economist to understand why that will help increase economic productivity, and it's intuitively obvious to the most casual observer that this can help prevent the onset of chronic disease and improve the quality of our lives.

This resolution urges the people of the United States to use the five prevention strategies to create healthier lifestyles. It encourages daily aspirin therapy, smoking cessation, colorectal cancer screening, annual flue immunizations, and breast cancer screenings that can save more than 100,000 lives each year by addressing behavioral choices.

In addition, the resolution suggests that the Congressional Budget Office process should reflect the significant savings associated with prevention of disease and injury. And that's of particular concern to me and something that I argue for in many other vocations and other legislation that we have to have the ability to do dynamic scoring when we follow policies that are likely to result in savings.

So the line in the bill, that it is the sense of the House we believe ''the congressional budget process should reflect the significant savings associated with investments in prevention of disease and injury,'' and that is an important concept and one that this Congress and the next Congress would do well to recognize and encourage our Congressional Budget Office to follow likewise.

I would like to thank the author of this resolution, Representative LUCILLE ROYBAL-ALLARD of California, for her leadership in improving the awareness of the benefits of prevention and her efforts to lower the number of preventable chronic diseases in the United States.

I encourage all of my colleagues to vote in favor of this resolution.

Ms. JACKSON-LEE of Texas. Mr. Speaker, today I stand for a commitment to making public healthcare a priority. I stand for universal healthcare as a universal right. I stand to support H. Res. 1381, ''expressing the sense of the House that there should be an increased Federal commitment prioritizing prevention and public health for all people in the United States.'' I thank my colleague, Representative ROYBAL-ALLARD for introducing this important resolution.

I would be remiss if I did not also thank my dear colleague from Michigan, Chairman of Judiciary, and Congressman JOHN CONYERS, for his tireless work on prioritizing healthcare in this Congress. His bimonthly meetings to bring together the healthcare community, congressional Members and staff, and other stakeholders; speaks to his commitment to making universal healthcare a priority.

Sadly, the United States is the only wealthy, industrialized nation that does not have a universal health care system. Some of the other disturbing healthcare statistics are that:

HEALTH INSURANCE STATISTICS

In 2006, the percentage of Americans without health insurance was 15.8 percent, or approximately 47 million uninsured people. Source: US Census Bureau.

Among the 84.2 percent with health insurance in 2006, coverage was provided through an employer 59.7 percent, purchased individually 9.1 percent, and 27.0 percent was Government funded (Medicare, Medicaid, Military). Source: US Census Bureau.

The primary reason given for lack of health insurance coverage in 2005 was cost (more than 50 percent), lost job or a change in employment (24 percent), Medicaid benefits stopped (10 percent), ineligibility for family insurance coverage due to age or leaving school (8 percent). Source: National Center for Health Statistics.

Medicare, a federally funded health insurance program that covers the health care of most individuals 65 years of age and over and disabled persons, accounted for 13.6 percent of health care coverage in 2006. Source: US Census Bureau.

Medicare operates with 3 percent overhead, non-profit insurance 16 percent overhead, and private (for-profit) insurance 26 percent overhead. Source: Journal of American Medicine 2007.

HEALTH CARE EXPENDITURES

In 2005, personal health care expenditures were paid by private health insurance 36 percent, federal government 35 percent, state and local governments 11 percent, and out-of-pocket payments 15 percent. Source: National Center for Health Statistics.

The United States spends twice as much on health care per capita ($7,129) than any other country * * * and spending continues to increase. In 2005, the national health care expenditures totaled $2 trillion. Source: National Center for Health Statistics.

75 percent of all health care dollars are spent on patients with one or more chronic conditions, many of which can be prevented, including diabetes, obesity, heart disease, lung disease, high blood pressure, and cancer. Source: Health Affairs.

From 2000 to 2006, overall inflation has increased 3.5 percent, wages have increased 3.8 percent, and health care premiums have increased 87 percent. Source: Kaiser Family Foundation.

Mr. Speaker, it is time we make public health a priority for all Americans. Children cannot do well in school when they do not have proper healthcare. Parents are afraid to change jobs because of possible loss or reductions in healthcare coverage. Our elders, our seniors have to choose between groceries and prescriptions.

Healthcare will become a priority when we make it one. This body has the power to create a fundamental change in how our country views and manages its healthcare system. We have the power to make a change in the lives of everyday Americans for the better. For it does not matter how much money you have, how many languages you speak, or how many degrees you have earned—without your health, you have nothing. A healthier America—starts right here, right now. Let's make it a priority Today!

Mr. Speaker, I encourage my colleagues to join me in supporting American families in their struggle to provide basic needs to their children, to their parents, and for themselves. I encourage my colleagues to remember that they hold the power of the pen and the vote, to make universal healthcare a priority.

Mr. Burgess. Having no other requests for time, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I have no further requests for time, I would urge support of this resolution for an increased commitment to prevention in public health, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and agree to the resolution, H. Res. 1381, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the resolution, as amended, was agreed to.

The title was amended so as to read: ''A resolution expressing the sense of the House that there should be an increased public and private commitment prioritizing prevention and public health for all people in the United States.''.

A motion to reconsider was laid on the table.

HEART FOR WOMEN ACT

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill

(H.R. 1014) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 1014

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Heart Disease Education, Analysis Research, and Treatment for Women Act'' or the ''HEART for Women Act''.

SEC. 2. REPORTING OF DATA IN APPLICATIONS FOR DRUGS, BIOLOGICS, AND DEVICES.

(a) DRUGS.—

(1) NEW DRUG APPLICATIONS.—Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) is amended—

(A) in paragraph (1), in the second sentence—

(i) by striking ''drug, and (G)'' and inserting ''drug; (G)''; and

(ii) by inserting before the period the following: ''; and (H) the information required under paragraph (7)''; and

(B) by adding at the end the following:

''(7)(A) With respect to clinical data in an application under this subsection, the Secretary may deny such an application if the application fails to meet the requirements of sections 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the sections referred to in subparagraph (A) to require that an application under this subsection include any clinical data possessed by the applicant that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.

''(C) Promptly after approving an application under this subsection, the Secretary shall, through an Internet site of the Department of Health and Human Services, make available to the public the information submitted to the Secretary pursuant to subparagraphs (A) and (B), subject to sections 301(j) and 520(h)(4) of this Act, subsection (b)(4) of section 552 of title 5, United States Code (commonly referred to as the 'Freedom of Information Act'), and other provisions of law that relate to trade secrets or confidential commercial information.

''(D) The Secretary shall develop guidance for staff of the Food and Drug Administration to ensure that applications under this subsection are adequately reviewed to determine whether the applications include the information required pursuant to subparagraphs (A) and (B).''.

(2) INVESTIGATIONAL NEW DRUG APPLICATIONS.—Section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) is amended—

(A) in paragraph (2), by striking ''Subject to paragraph (3),'' and inserting ''Subject to paragraphs (3) and (5),'' ; and

(B) by adding at the end the following:

''(5)(A) The Secretary may place a clinical hold (as described in paragraph (3)) on an investigation if the sponsor of the investigation fails to meet the requirements of section 312.33(a) of title 21, Code of Federal Regulations.

''(B) The Secretary shall modify the section referred to in subparagraph (A) to require that reports under such section include any clinical data possessed by the sponsor of the investigation that relates to the safety or effectiveness of the drug involved by gender, age, and racial subgroup.''.

(b) BIOLOGICS LICENSE APPLICATIONS.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(k) The provisions of section 505(b)(7) of the Federal Food, Drug, and Cosmetic Act (relating to clinical data submission) apply with respect to an application under subsection (a) of this section to the same extent and in the same manner as such provisions apply with respect to an application under section 505(b) of such Act.''.

(c) DEVICES.—

(1) PREMARKET APPROVAL.—Section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e) is amended—

(A) in subsection (c)(1)—

(i) in subparagraph (G)—

(I) by moving the margin 2 ems to the left; and

(II) by striking ''and'' after the semicolon at the end;

(ii) by redesignating subparagraph (H) as subparagraph (I); and

(iii) by inserting after subparagraph (G) the following subparagraph:

''(H) the information required under subsection (d)(7); and''; and

(B) in subsection (d), by adding at the end the following paragraph:

''(7) To the extent consistent with the regulation of devices, the provisions of section 505(b)(7) (relating to clinical data submission) apply with respect to an application for premarket approval of a device under subsection (c) of this section to the same extent and in the same manner as such provisions apply with respect to an application for premarket approval of a drug under section 505(b).''.

(2) INVESTIGATIONAL DEVICES.—Section 520(g)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(g)(2)) is amended by adding at the end the following subparagraph:

''(D) To the extent consistent with the regulation of devices, the provisions of section 505(i)(5) (relating to individual study information) apply with respect to an application for an exemption pursuant to subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to an application for an exemption under section 505(i).''.

(d) RULES OF CONSTRUCTION.—This Act and the amendments made by this Act may not be construed—

(1) as establishing new requirements under the Federal Food, Drug, and Cosmetic Act relating to the design of clinical investigations that were not otherwise in effect on the day before the date of the enactment of this Act; or

(2) as having any effect on the authority of the Secretary of Health and Human Services to enforce regulations under the Federal Food, Drug, and Cosmetic Act that are not expressly referenced in this Act or the amendments made by this Act.

(e) APPLICATION.—This section and the amendments made by this section apply only with respect to applications received under section 505 or 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355, 360e) or section 351 of the Public Health Service Act (42 U.S.C. 262) on or after the date of the enactment of this Act.

SEC. 3. REPORTING AND ANALYSIS OF PATIENT SAFETY DATA.

(a) DATA STANDARDS.—Section 923(b) of the Public Health Service Act (42 U.S.C. 299b–23(b)) is amended by adding at the end the following: ''The Secretary shall provide that all nonidentifiable patient safety work product reported to and among the network of patient safety databases be stratified by sex.''.

(b) USE OF INFORMATION.—Section 923(c) of the Public Health Service Act (42 U.S.C. 299b–23(c)) is amended by adding at the end the following: ''Such analyses take into account data that specifically relates to women and any disparities between treatment and the quality of care between males and females.''.

SEC. 4. QUALITY OF CARE REPORTS BY THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY.

Section 903 of the Public Health Service Act (42 U.S.C. 299a–1) is amended—

(1) in subsection (b)(1)(B), by inserting before the semicolon the following: '', including quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases''; and

(2) in subsection (c), by adding at the end the following:

''(4) ANNUAL REPORT ON WOMEN AND HEART DISEASE.—Not later than September 30, 2009, and annually thereafter, the Secretary, acting through the Director, shall prepare and submit to Congress a report concerning the findings related to the quality of and access to care for women with heart disease, stroke, and other cardiovascular diseases. The report shall contain recommendations for eliminating disparities in, and improving the treatment of, heart disease, stroke, and other cardiovascular diseases in women.''.

SEC. 5. EDUCATIONAL CAMPAIGNS.

(a) DISTRIBUTION OF EDUCATIONAL MATERIAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall develop and distribute to females who are age 65 or older, physicians, and other appropriate healthcare professionals, educational materials relating to the prevention, diagnosis, and treatment of heart disease, stroke, and cardiovascular diseases in women. The Secretary may carry out this subsection through contracts with public and private nonprofit entities.

(b) HEALTHCARE PROFESSIONAL EDUCATIONAL CAMPAIGN.—The Secretary, acting through the Bureau of Health Professions of the Health Resources and Services Administration, shall conduct an education and awareness campaign for physicians and other healthcare professionals relating to the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women. The Bureau of Health Professions may carry out this subsection through contracts with public and private nonprofit entities.

SEC. 6. EXTENSION OF WISEWOMAN PROGRAM.

Section 1509 of the Public Health Service Act (42 U.S.C. 300n–4a) is amended—

(1) in subsection (a)—

(A) by striking the heading and inserting ''IN GENERAL.—''; and

(B) in the matter preceding paragraph (1), by striking ''may make grants'' and all that follows through ''purpose'' and inserting the following: ''may make grants to such States for the purpose''; and

(2) in subsection (d)(1), by striking ''there are authorized'' and all that follows through the period and inserting ''there are authorized to be appropriated $37,000,000 for fiscal year 2009, $38,850,000 for fiscal year 2010, $40,792,500 for fiscal year 2011, $42,832,000 for fiscal year 2012, and $44,974,000 for fiscal year 2013.''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from New Jersey (Mr. PALLONE) and the gentleman from Texas (Mr. BURGESS) each will control 20 minutes.

The Chair recognizes the gentleman from New Jersey.

GENERAL LEAVE

Mr. PALLONE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days to revise and extend their remarks and include extraneous material on the bill under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from New Jersey?

There was no objection.

Mr. PALLONE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in strong support of H.R. 1014, the Heart Disease Education, Analysis Research, and Treatment (HEART) for Women Act. This

legislation will go a long way in improving the prevention, diagnosis, and treatment of heart disease, stroke, and other cardiovascular diseases in women.

Heart disease and other forms of cardiovascular disease are the leading cause of death in the United States and a major cause of disability. More than 850,000 people die of cardiovascular disease in the U.S. annually, representing nearly 36 percent of all U.S. deaths.

Although heart disease is sometimes thought of as ''man's disease,'' one in three American women die of heart disease and other cardiovascular diseases, making it the leading cause of death for both women and men in the United States. Heart disease is the leading cause of death among women aged 65 years and older and is the second and third leading cause of death among women aged 45 to 64 years, and women aged 25 to 44 years respectively.

H.R. 1014 proposes to reduce the cardiovascular disease death rate for women through improved health education, gender-specific analysis and research, and increased access to screening for women. H.R. 1014 authorizes the Department of Health and Human Services to educate health care professionals and older women about unique aspects of care in the prevention, diagnosis, and treatment of women with heart disease and stroke.

H.R. 1014 requires clinical data that is already being reported to the Federal Government by drug and advice manufacturers to be gender-specific. Additionally, the bill before us authorizes the expansion of the CDC's Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program. This program, currently available in only 20 States, provides free cardiovascular screenings to low-income uninsured women.

H.R. 1014 is the result of the leadership of Representative LOIS CAPPS and BARBARA CUBIN and the hard work and cooperation of the Democratic and Republican members of the Energy and Commerce Committee. The bill enjoys the support of a majority of the House of Representatives and numerous public health organizations, including the American Heart Association and the American Stroke Association, the Society for Women's Health Research, and WomenHeart: The National Coalition for Women with Heart Disease.

I strongly urge all of my colleagues to vote to improve the health of women by passing this bill.

I reserve the balance of my time.

Mr. BURGESS. Mr. Speaker, in deference to the primary sponsor of the bill, I will reserve the balance of my time.

Mr. PALLONE. Mr. Speaker, I yield once again to the gentlewoman from California, the sponsor of the bill, the vice-chair of the Health Subcommittee and obviously someone who's worked very hard on so many health care initiatives, 3 minutes.

Mrs. CAPPS. Mr. Speaker, I rise in strong support of H.R. 1014, the HEART for Women Act. I thank my colleague for yielding to me, and I thank the lead co-sponsor of this bill, Congresswoman BARBARA CUBIN of Wyoming.

I was proud to first introduce the HEART for Women Act in 2006 with the help of organizations such as the American Heart Association, WomenHeart, and the Society for Women's Health Research. Since then, the list of supporters has grown to over 50 organizations, 237 cosponsors in the House, and 47 cosponsors of the Senate companion legislation.

This legislation was borne out of the realization that despite heart disease being the number one killer of women, too few people are aware of it. In 2006, only 21 percent of women identified heart disease as women's greatest health problem, and too few people were aware that heart disease manifests itself differently in women than in men.

The HEART for Women Act would improve the diagnosis and treatment of cardiovascular disease in women in three important ways.

First, it would authorize educational campaigns aimed at health providers and older women to make them more aware of the risks for cardiovascular disease among women.

Secondly, it will authorize the expansion of CDC's highly successful WISEWOMAN program, to which our chairman alluded. Since 2000, WISEWOMAN has been providing screenings for low-income uninsured women. The CDC has touted the success of WISEWOMAN in that they have screened over 79,000 women in need, identified over 7,600 new cases of high blood pressure, over 7,900 new cases of high cholesterol, and over 1,000 cases of diabetes.

I am proud that this legislation will play a part in reaching hundreds of thousands of new women in the years to come.

Finally, H.R. 1014 will improve the way we collect and analyze research data. By directing the FDA to collect data about safety and the efficacy of new and investigational drugs and devices according to gender, age, and racial subgroups.

We will help women and their health care providers better understand which course of treatment may yield the best outcome.

Once again, I thank our colleague Congresswoman CUBIN, the coalition of supporters, and the Energy and Commerce Committee majority and minority staff.

I urge my colleagues to vote ''yes'' on H.R. 1014.

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Mr. BURGESS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 1014. This legislation encourages manufacturers of drugs and devices to report to the Food and Drug Administration gender and race-specific information on their products. The legislation also authorizes the Secretary to develop a public awareness campaign relating to the prevention, diagnosis, and treatment of heart disease, stroke, and cardiovascular diseases in women.

Lastly, the bill authorizes the WISEWOMAN program at the Centers for Disease Control which provides heart disease and stroke prevention screening, such as tests for high blood pressure and high cholesterol, to low-come uninsured and underinsured women.

I urge Members to support the bill.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I urge support of this important legislation relative to heart disease.

Mr. RADANOVICH. Mr. Speaker, I would like to thank my colleagues Mrs. CAPPS and Mrs. CUBIN for sponsoring H.R. 1014, the Heart Disease Education, Analysis Research and Treatment, or HEART, for Women Act. I lend my strong support for its swift passage both here and on the House floor Heart for Women Act will be a vital step forward in addressing the disparities in the diagnosis and treatment of heart disease and stroke between men and women.

Heart disease, stroke, and other cardiovascular diseases are the number one killer of women, both nationally and in my home state of California. They account for over 30 percent of all female deaths in California, and there are currently approximately 43 million adult women living with one or more forms of heart disease.

These numbers are very telling about the need for this reporting and authorization. But to really understand the importance of this legislation, you must look at how this can affect the lives of any one of those 43 million women living with heart disease today. I personally have seen the effects it can have—the struggles for the individual and the difficulties it can place on a family—through the experiences of a longtime and valued member of my staff But also through her, I have seen the courage displayed by women living with heart disease. They are dedicated to this cause, so that others may have it a little easier than they have. For her and all women living with this disease, this legislation today is a triumph and a testament to their strength.

Thank you again to the bill's sponsors, and I encourage all my colleagues to fully support this extremely important legislation.

Mr. PALLONE. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from New Jersey (Mr. PALLONE) that the House suspend the rules and pass the bill, H.R. 1014, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds being in the affirmative, the ayes have it.

Mr. BURGESS. Mr. Speaker, I object to the vote on the ground that a quorum is not present and make the point of order that a quorum is not present.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the

Chair's prior announcement, further proceedings on this motion will be postponed.

The point of no quorum is considered withdrawn.

RYAN HAIGHT ONLINE PHARMACY CONSUMER PROTECTION ACT OF 2008

Mr. PALLONE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 6353) to amend the Controlled Substances Act to address online pharmacies, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 6353

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ryan Haight Online Pharmacy Consumer Protection Act of 2008''.

SEC. 2. REQUIREMENT OF A VALID PRESCRIPTION FOR CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.

Section 309 of the Controlled Substances Act (21 U.S.C. 829) is amended by adding at the end the following:

''(e) CONTROLLED SUBSTANCES DISPENSED BY MEANS OF THE INTERNET.—

''(1) No controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription.

''(2) As used in this subsection:

''(A) The term 'valid prescription' means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by—

''(i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or

''(ii) a covering practitioner.

''(B)(i) The term 'in-person medical evaluation' means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

''(ii) Nothing in clause (i) shall be construed to imply that 1 in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the usual course of professional practice.

''(C) The term 'covering practitioner' means, with respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who—

''(i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and

''(ii) is temporarily unavailable to conduct the evaluation of the patient.

''(3) Nothing in this subsection shall apply to—

''(A) the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine; or

''(B) the dispensing or selling of a controlled substance pursuant to practices as determined by the Attorney General by regulation, which shall be consistent with effective controls against diversion.''.

SEC. 3. AMENDMENTS TO THE CONTROLLED SUBSTANCES ACT RELATING TO THE DELIVERY OF CONTROLLED SUBSTANCES BY MEANS OF THE INTERNET.

(a) IN GENERAL.—Section 102 of the Controlled Substances Act (21 U.S.C. 802) is amended by adding at the end the following:

''(50) The term 'Internet' means collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio.

''(51) The term 'deliver, distribute, or dispense by means of the Internet' refers, respectively, to any delivery, distribution, or dispensing of a controlled substance that is caused or facilitated by means of the Internet.

''(52) The term 'online pharmacy'—

''(A) means a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet; and

''(B) does not include—

''(i) manufacturers or distributors registered under subsection (a), (b), (d), or (e) of section 303 who do not dispense controlled substances to an unregistered individual or entity;

''(ii) nonpharmacy practitioners who are registered under section 303(f) and whose activities are authorized by that registration;

''(iii) any hospital or other medical facility that is operated by an agency of the United States (including the Armed Forces), provided such hospital or other facility is registered under section 303(f);

''(iv) a health care facility owned or operated by an Indian tribe or tribal organization, only to the extent such facility is carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act;

''(v) any agent or employee of any hospital or facility referred to in clause (iii) or (iv), provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of health care facilities specified in clause (iv), only to the extent such individuals are furnishing services pursuant to the contracts or compacts described in such clause;

''(vi) mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance;

''(vii) a person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States;

''(viii) a pharmacy registered under section 303(f) whose dispensing of controlled substances via the Internet consists solely of—

''(I) refilling prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (55); or

''(II) filling new prescriptions for controlled substances in schedule III, IV, or V, as defined in paragraph (56); or

''(ix) any other persons for whom the Attorney General and the Secretary have jointly, by regulation, found it to be consistent with effective controls against diversion and otherwise consistent with the public health and safety to exempt from the definition of an 'online pharmacy'.

''(53) The term 'homepage' means the opening or main page or screen of the website of an online pharmacy that is viewable on the Internet.

''(54) The term 'practice of telemedicine' means, for purposes of this title, the practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist) who is at a location remote from the patient and is communicating with the patient, or health care professional who is treating the patient, using a telecommunications system referred to in section 1834(m) of the Social Security Act, which practice—

''(A) is being conducted—

''(i) while the patient is being treated by, and physically located in, a hospital or clinic registered under section 303(f); and

''(ii) by a practitioner—

''(I) acting in the usual course of professional practice;

''(II) acting in accordance with applicable State law; and

''(III) registered under section 303(f) in the State in which the patient is located, unless the practitioner—

''(aa) is exempted from such registration in all States under section 302(d); or

''(bb) is—

''(AA) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

''(BB) registered under section 303(f) in any State or is utilizing the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

''(B) is being conducted while the patient is being treated by, and in the physical presence of, a practitioner—

''(i) acting in the usual course of professional practice;

''(ii) acting in accordance with applicable State law; and

''(iii) registered under section 303(f) in the State in which the patient is located, unless the practitioner—

''(I) is exempted from such registration in all States under section 302(d); or

''(II) is—

''(aa) an employee or contractor of the Department of Veterans Affairs who is acting in the scope of such employment or contract; and

''(bb) registered under section 303(f) in any State or is using the registration of a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

''(C) is being conducted by a practitioner—

''(i) who is an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act;

''(ii) acting within the scope of the employment, contract, or compact described in clause (i); and

''(iii) who is designated as an Internet Eligible Controlled Substances Provider by the Secretary under section 311(g)(2);

''(D)(i) is being conducted during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act; and

''(ii) involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates, provided that such designation shall not be subject to the procedures prescribed by subchapter II of chapter 5 of title 5, United States Code;

''(E) is being conducted by a practitioner who has obtained from the Attorney General a special registration under section 311(h);

''(F) is being conducted—

''(i) in a medical emergency situation—

''(I) that prevents the patient from being in the physical presence of a practitioner registered under section 303(f) who is an employee or contractor of the Veterans Health Administration acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor;

''(II) that prevents the patient from being physically present at a hospital or clinic operated by the Department of Veterans Affairs registered under section 303(f);

''(III) during which the primary care practitioner of the patient or a practitioner otherwise practicing telemedicine within the meaning of this paragraph is unable to provide care or consultation; and